

# PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
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Docket System ✓  
Status Report ✓  
Docket Book ✓

10/19/04 WJO

**PCT**

WRITTEN OPINION

(PCT Rule 66)

14 JAN 2005

Date of Mailing (day/month/year) <b>19 AUG 2004</b>	
Applicant's or agent's file reference <b>DC-0228</b>	
International application No. <b>PCT/US03/24148</b>	International filing date (day/month/year) <b>31 July 2003 (31.07.2003)</b>
Priority date (day/month/year) <b>31 July 2002 (31.07.2002)</b>	
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): A61K 38/28; 39/395 and US Cl.: 514/3; 424/130.1</b>	
Applicant <b>TRUSTEES OF DARTMOUTH COLLEGE</b>	

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 30 November 2004 (30.11.2004).

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Kevin E. Weddington Telephone No. (703) 308-1235
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Form PCT/IPEA/408 (cover sheet)(July 1998)

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WRITTEN OPINION

International application No.

PCT/US03/24148

I. Basis of the opinion

1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:
  - pages 1-20, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:
  - pages 21, as originally filed
  - pages NONE, as amended (together with any statement) under Article 19
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:
  - pages NONE, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:
  - pages 1 and 2, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

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**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1</u>	NO
Industrial Applicability (IA)	Claims <u>1</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claim 1 meet the criteria set out in PCT Article 33(4) as having industrial applicability in the pharmaceutical art.

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by LaRossa.

LaRossa teaches anti-body or functional fragments proteins that include monocyte chemoattractant protein-1 (MCP-1) to treat inflammatory condition.

Claim 1 lacks an inventive step under PCT Article 33(3) as being obvious over LaRossa.

LaRossa was discussed above supra for its intended use.

The instant invention differs from the cited reference in that the cited reference does not teach the instant proteins are used to treat pain. However, one skilled in the art would have been motivated to use the instant proteins to treat pain since the instant proteins (possessing anti-inflammatory properties) are routinely used to treat pain in the absence of evidence to the contrary.

**WRITTEN OPINION**

International application No.

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 1 is objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claim is not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because:

Applicants' description does not contain any test results or experimental data showing the instant proteins will, in fact, prevent pain in a mammal not presently at risk of or predisposed to developing such a condition that will cause pain.